



S/N: 10/036,490

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#4

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	MERON et al.	Examiner:	K. Padmanabhan
Serial No.:	10/036,490	Group Art Unit:	1641
Filed:	January 7, 2002	Attorney Docket No.:	P-2038-US1
Title:	A SYSTEM FOR DETECTING OF SUBSTANCES		

PRELIMINARY AMENDMENT

Assistant Commissioner for Patents
Washington, DC 20231

Sir:

Kindly amend the above-identified application as follows:

In the Specification:

Please change the title to --System and Method For Determining the Presence of a Substance In-Vivo --.

On page 1, line 4, please insert:

--Prior Application

This application is a continuation of prior U.S. application serial no. 09/487,337 filed 19 January 2000 and entitled "A System For Detecting Of Substances".--

In the Claims:

Please cancel claims 6 and 17 without prejudice.

Please amend the claims as follows:

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1. (Amended) A system for determining in vivo the presence and/or concentration of a biological and/or chemical substance in a body lumen comprising:

a solid support, the support being inserted into a body lumen and having immobilized thereon at least one reactant which when in the presence of the substance reacts with the substance resulting in an optical change; and
a detecting unit, in communication with the support.

13. (Amended) A system according to claim 1 wherein the reactant is polymethylmethacrylate having thrombin linked thereon.

14. (Amended) A system according to claim 1, the detecting unit imaging a reaction between the reactant and the substance.

16. A system according to claim 50 wherein the support is transparent to illumination emitted from the illuminating element.

20. (Amended) A system according to claim 1 further comprising a monitoring unit in communication with the support, said monitoring unit locating the support in the body lumen.

22. (Amended) A system according to claim 21 wherein the monitoring unit comprises a reception system receiving transmitted output from said transmitting unit thereby locating the support along a pre-prepared map of the lumen.

23. (Amended) A method for determining in vivo the presence and/or concentration of a biological and/or chemical substance in a body lumen comprising the steps of:

inserting into a body lumen a solid support, said support having immobilized thereon at least one reactant which, when in the presence of the substance, reacts with

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the substance resulting in an optical change and said support being in communication with a detecting unit; and
receiving information from the detecting unit.

49. (Amended) A diagnostic device for the detection of blood or blood components in a body lumen comprising:

a plastic support, the support being inserted into the body lumen and having immobilized thereon at least one reactant reacting with the blood or blood components resulting in an optical change; and

a detecting unit, in communication with the support.

Please add new claim 50 as follows:

50. (New) A system according to claim 15 wherein the combination of the support and the reactant is transparent to the illumination emitted from the illuminating element.

REMARKS

On January 7, 2002 the present Application was filed as a continuation of the parent application (January 5, 2002 being a Saturday) Serial No. 09/487,337.

Applicants thank the Examiner for the in-person interview with Applicants' attorney on October 18, 2001 regarding the parent application. Applicant has carefully studied the outstanding Office Action of July 5, 2001 in the parent application. The present Amendment is intended to be fully responsive to all points of rejection raised by the Examiner in that Office Action and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application is respectfully requested.

Claims 1-16, 18-22, 45, 46, and 49-50 are pending in the application. Claims 1-22, 45, 46, and 49 were rejected in the Office Action. The title has been amended, claims 1, 13,

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14, 16, 20, 22, 23 and 49 have been amended, and claims 6 and 17 have been cancelled. Claim 50 has been added in order to point out more particularly what the Applicants regard as their invention.

The amendments add no new matter. The amendments have been entered to further clarify the subject matter the applicants regard as their invention, to correct typographical mistakes, and in response to the Examiner's 35 U.S.C. § 112 rejections and objections to the title. Explanations for the amendments have been provided. None of the amendments narrow the scope of the amended claims. Accordingly, these amendments are not subject to the complete bar against the use of the Doctrine of Equivalents as outlined in *Festo Corporation v. Shoketsu Kinsoku Kogyo Kabushiki Co., Ltd.*

Attached hereto is a marked-up version of the changes made to the specification and to the claims by the current amendment. The attached page is captioned "Version With Markings to Show Changes Made."

Examiner's Remarks on the Specification

In the Office Action, the Examiner objected to the title. During the October 18, 2001 Interview, agreement was reached regarding a title proposed by Applicants. The title has been amended in accordance with this proposal. Therefore, Applicants submit that the Examiner's objection has been overcome.

In the Office Action, the Examiner objected to the disclosure due to the large spaces on certain pages. During the October 18, 2001 Interview, Applicants' attorney explained that these spaces were intentional, and were due to formatting choices. The Examiner agreed that the spaces were therefore acceptable. Therefore, Applicants' submit that the Examiner's objection has been overcome.

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Examiner's Claims Rejections

35 U.S.C. § 112

In the Office Action, the Examiner had rejected claims 1-22, 45, 46 and 49 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants' regard as their invention.

In the Office Action, the Examiner rejected the claims under 35 U.S.C. § 112 for various reasons. During the October 18, 2001 Interview, Applicants' attorney and the Examiner agreed that an amendment would overcome the Examiner's rejections regarding the terms "capable" and "operable." Applicants have made such amendments, and further have amended the claims in response to the Examiner's other 35 U.S.C. § 112 rejections. In light of these amendments, Applicants' submit that the Examiner's objection has been overcome.

35 U.S.C. § 102

In the Office Action, the Examiner rejected claims 1-22, 45, 46 and 49 under 35 U.S.C. § 102(b) as being anticipated by Willner et al. (WO 97/45720) ("Willner"). The Examiner rejected claims 1-6, 8-9, 14-15, 19-21, 45 and 49 under 35 U.S.C. § 102(b) as being anticipated by Desai et al., U.S. Pat 5,362,478 ("Desai").

During the October 18, 2001 Interview, Applicants' attorney argued that neither Willner nor Desai anticipated claims 1-22, 45, 46 and 49, as pending at that time. Applicants' attorney and the Examiner therefore agreed that the Examiner's rejections under 35 U.S.C. § 102(b) would be withdrawn. Furthermore, Applicants' assert that neither Willner nor Desai anticipate any of Applicants' currently pending claims. Therefore, Applicants' submit that the Examiner's rejection of claims 1-22, 45, 46 and 49 under 35 U.S.C. § 102(b) as being anticipated by Willner, and his rejection of claims 1-6, 8-9, 14-15, 19-21, 45 and 49 under 35 U.S.C. § 102(b) as being anticipated by Desai have been overcome, and Applicants respectfully submit that claims 1-16, 18-22, 45, 46, and 49-50 are allowable.

Applicants note that none of the amendments to the claims herein are in response to the above discussed prior art rejections, and Applicants further note that the agreement with

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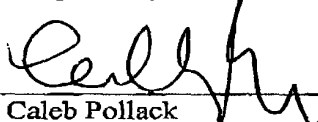
the Examiner regarding the prior art was unrelated to the amendments to the claims. The amendments to the claims are discussed more fully above.

Conclusion

In view of the above amendments and remarks it is submitted that the application is now in condition for allowance. Prompt notice of allowance is respectfully requested. Applicant asserts that the present invention is new, non-obvious and useful. Prompt consideration and allowance of the claims is respectfully requested.

Please charge any fees associated with this paper to Deposit Account No. 05-0649.

Respectfully submitted,



Caleb Pollack
Attorney for Applicants
Registration No. 37,912

Dated: March 25, 2002

Eitan, Pearl, Latzer & Cohen-Zedek
One Crystal Park, Suite 210
2011 Crystal Drive
Arlington, VA 22202-3709
Tel: (703) 486-0600
Fax: (703) 486-0800

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification:

Please change the title to --System and Method For Determining the Presence of a Substance In-Vivo --.

On page 1, line 4, please insert:

--Prior Application

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In the Claims:

Please cancel claims 6 and 17 without prejudice.

Please amend the claims as follows:

1. (Amended) A system for determining in vivo the presence and/or concentration of a biological and/or chemical substance in a body lumen comprising:

a solid support, the support being inserted into a body lumen and having immobilized thereon at least one reactant [capable of reacting] which when in the presence of the substance reacts with the substance resulting in an optical change; and

a detecting unit, in communication with the support[, capable of detecting a reaction resulting in an optical change between the reactant and the substance].

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13. (Amended) A system according to claim 1 wherein the reactant is [polymethylmetacrylate] polymethylmethacrylate having thrombin linked thereon.

14. (Amended) A system according to claim 1, [wherein] the detecting unit [is capable of] imaging a reaction between the reactant and the substance.

16. A system according to claim [15] 50 wherein the support is transparent to illumination emitted from the illuminating element.

20. (Amended) A system according to claim 1 further comprising a monitoring unit in communication with the support, said monitoring unit [capable of] locating the support in the body lumen.

22. (Amended) A system according to claim 21 wherein the monitoring unit comprises a reception system [operable with the transmitting unit, said reception system capable of] receiving transmitted output from said transmitting unit thereby locating the support along a [pre prepared] pre-prepared map of the lumen.

23. (Amended) A method for determining in vivo the presence and/or concentration of a biological and/or chemical substance in a body lumen comprising the steps of:

inserting into a body lumen a solid support, said support having immobilized thereon at least one reactant [capable of reacting] which, when in the presence of the substance, reacts with the substance resulting in an optical change and said support being in communication with a detecting unit [that is capable of detecting a reaction resulting in an optical change between the reactant and the substance]; and

[b)] receiving information from the detecting unit.

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49. (Amended) A diagnostic device for the detection of blood or blood components in a body lumen [comprising] comprising:

a plastic support, the support being inserted into the body lumen and having immobilized thereon at least one reactant [capable of] reacting with the blood or blood components resulting in an optical change; and

a detecting unit, in communication with the support[, capable of detecting a reaction resulting in an optical change between the reactant and the blood or blood components].

Please add new claim 50 as follows:

50. (New) A system according to claim 15 wherein the combination of the support and the reactant is transparent to the illumination emitted from the illuminating element.